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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,640	12/08/2000	Anthony J. McHugh	ILL03-027-US	2399

43320 7590 06/09/2005

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EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 06/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/733,640	MCHUGH ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-8,17-19,34,38 and 49-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-8, 17-19, 34, 38, and 49-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Amendments and Remarks received March 21, 2005 is acknowledged. Claims **1, 3-8, 17-19, 34, 38, and 49-72** are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 66 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 66 is directed to a composition having a viscosity such that the composition can be dispensed through a 20-gauge needle. The specification does not define what viscosity is capable of being dispensed from a 20-gauge needle and thus the viscosity is unclear. Further clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 5-7, 17-18, 34, 38, 51-53, 55-56, 58-60, 66-67 are rejected under 35 U.S.C. 102(b) as being anticipated by US patent 5,525,646 to Lundgren et al.

Lundgren discloses a bioresorbable material and an article of manufacture made of such material for medical use to be implanted into a living organism. See column 1, lines 5-10. Lundgren et al disclose the need for implant articles to have both dimension stability (mechanical strength) to retain the shape of the implant during the healing process and malleability so that the material can take the shape of the location it is contained within. See column 1, lines 15-50. Therefore, Lundgren et al disclose a bioresorbable material that comprises at least one amorphous polymer or copolymer selected from the group consisting of poly-d,l-lactide, and copolymers of poly-d,l-lactide and polycaprolactone, poly-l-lactide, or polytrimethylene and at least one crystalline polymer selected from the group consisting of poly-l-lactide, polycaprolactone and polydioxanone; and a plasticizer (instant solvent, acetyl tributyl citrate). The composition is a vehicle for the delivery of active agents. See column 5, lines 40-50. The polymer material is made by mixing the polymers and plasticizer to provide a homogenous **solution**. The solution is then allowed to solidify overnight. Lundgren discloses implanting the polymer material into the periodontal defects of monkeys wherein the material is inserted into the oral cavity. See column 10, lines 34-45.

Note that the limitation of claim 58 must be inherent since the prior art and the instant claims recite the same structure with the same components unless the instant multilayer configuration is due to conditions that are not recited in the claims. If the latter is the case, then the applicant must include the conditions which provides the limitation.

With regard to claim 66, it is the examiner's position since the prior art teaches a polymer *solution*, it is capable of being dispensed from a 20-gauge needle.

Response to Arguments

Applicant argues that Lundgren discloses biodegradable compositions for use in tissue regeneration, where the composition is both malleable and dimensionally stable. Applicant acknowledges the reference describes a malleable composition as having a shape that "can be adapted to the shape of the region to be covered, often in a three-dimensional fashion." Applicant argues that administration of the compositions involves forming the composition into the desired shape and then surgically inserting the shaped composition into the patient. Thus, applicant argues there is no disclosure in Lundgren of an *injectable* composition. Applicant argues that the disclosed compositions are not capable of being administered by injection.

Applicant's arguments filed 3/21/05 have been fully considered but they are not persuasive. Firstly, the examiner points out that "injectable" in claim 1 occurs in the preamble, and a preamble is generally not accorded any patentable weight where it merely recites the **purpose of a process or the intended use of a structure**, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

However, for arguendo sake the examiner points out the following. Firstly, as recognized by applicant the composition is described as malleable without shape. Malleability refers to a material that has little or no memory so that the material can be adapted to the shape of the region to be covered. See column 1, lines 32-44. Therefore, the material is malleable until the polymer solution is solidified to provide a three dimensional shape. The examiner further points to column 9, wherein the polymer material exists in a polymer *solution* and is solidified over night to form the film. It is pointed out that the instant invention also exists in a polymer solution

until it solidifies. Thus, with regard to the composition claims Lundgren's composition is *capable* of being injected and the method of administering the implant, i.e. injection using a needle, does not hold patentable weight.

Secondly and in particular reference to the method of administering claim 34, it is pointed out that the claim broadly recites "inserting an *injectable* composition". Summarily, the claim is directed to a method of administering a bioactive agent comprising inserting a composition that is *capable* of being injected (injectable) into a organism. The claim does not require the composition to be administered via a needle. The examiner points out that "injectable" is given its broadest and most reasonable interpretation. Webster's defines injectable as: 1a) to introduce into something forcefully b) to force a fluid into (as for medical purpose); **2 to introduce as an element or factor in or into some situation or subject**. Keeping this definition in mind, the examiner points out that Lundgren implants the polymer material in the periodontal defects in the oral cavity of monkeys by inserting the material into the defect area. This clearly reads on the definition 2 "introducing an element into a subject".

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e. the composition has a viscosity low enough to flow thorough a 18-20 gauge needle) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

For the reasons above, the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 5, 34, 38, 49-49, 51, and 58-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shukla (6,432,438) in view of WO 88/07366 to Bateman et al.

Shukla teaches a biodegradable vehicle containing a drug, at least two plasticizers (solvent) selected from NMP (biocompatible solvent), PEG, triacetin (biocompatible component solvent), etc, and at least one biodegradable polymer, which is injected into an organism. See abstract. The composition is injected with a syringe, implanted, or it is applied directly to tissues of animals and humans. See column 3, lines 40-45. The composition is in the form of a viscous liquid, gel or paste. See column 4, lines 5-10. The polymers may be selected from polyesters, polyorthoesters, polyanhydrides, polyaminoacids, pseudopolyamino acids, polyamides, polyalkylcyanoacrylates, and polyphosphazenes. A mixture of polymers may be used to tailor either the release characteristics of BAS in the biodegradable delivery system, or the degradation characteristics of the biodegradable delivery system or both. See column 5, lines 55-67. The

reference teaches the blending of two different biodegradable polymers with varying crystallinity and amorphous states to tailor release characteristics of the delivery system. See column 4, lines 25-35, column 9, lines 30-35, and example 29. The method of mixing the polymer, solvent, and drug are taught in examples. Note that NMP has a miscibility in water of 7% or less as defined by instant specification. The vehicle is sterilized before packing. See column 3, lines 14-15.

Although, Shukla teaches the blending of polymers according to their properties to manipulate release rate, Shukla et al do not exemplify the use of a polymer blend specifically comprising an amorphous polymer and a crystalline polymer.

Bateman et al disclose a tablet composition containing a crystalline polymer and an amorphous polymer. See abstract. Bateman et al teach partially crystalline polymers provide for an immediate release whereas amorphous polymers provide for a prolonged release. See page 7, lines 25-35. Further, Bateman teaches that blending crystalline and amorphous polymers in various ratios, a range of active release can be provided. See page 8, lines 1-6.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Shukla et al and Bateman et al and specifically utilize a polymer blend of an amorphous polymer and a crystalline polymer. One would have been motivated to do so since Bateman teaches that amorphous polymers tend to provide a sustained release whereas crystalline polymers provide a immediate release, and by varying the ratio of both types of polymer, the desired release rate can be obtained. Therefore, one would have been motivated to look to Bateman's specific teaching that the instant polymer blend provides for the desired release rate and apply it to Shukla's broad teaching that varying the properties, such as

crystallinity and amorphous states of the biodegradable polymers tailors the release rate of the delivery device, to manipulate the release rate of Shukla's implant.

Response to Arguments

Applicant argues that Shukla teaches injectable composition whereas Bateman teaches solid tablet formulations. Thus, applicant argues that an attempt to incorporate the tablet formulation of Bateman into Shukla is improper since it would render the primary reference inoperable.

Applicant's arguments filed 3/21/05 have been fully considered but they are not persuasive. The test for obviousness is not whether the features of a secondary reference may be **bodily incorporated** into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In instant case, the premise of the rejection is not to incorporate Bateman's tablet into Shukla. The examiner relies on Bateman to demonstrate the state of the art wherein it is known to blend polymers with different crystallinity to manipulate the release rate. Shukla generally teaches mixing a blend of polymers to tailor either the release characteristics of biologically active substance (BAS) in the biodegradable delivery system, or the degradation characteristics of the biodegradable delivery system or both. See column 5, lines 55-67. Shukla teaches the blending of two or more different biodegradable polymers with varying crystallinity to tailor release characteristics of the delivery system. See column 4, lines 25-35. Moreover, Shukla teaches using blends of polymers with different crystallinity and hydrophobicity can result in a biodegradable vehicle with varying

degradation rates. See column 7, lines 40-45, and example 29. Although, it is the examiner's position that Shukla does *suggest* the use of a crystalline polymer with an amorphous to tailor the release rate, the examiner relies on Bateman to further provide motivation to a skilled artisan to utilize the polymer blend suggested by Shukla. Bateman clearly states on page 8 that "blending crystalline and amorphous polymer in various ratios, the tablets having a range of active ingredients release characteristics can be provided." Although, Bateman is directed to tablet formulations, Bateman teaches the state of the art wherein it is known to combine a crystalline polymer with an amorphous polymer to manipulate the release rate of the vehicle. The fact that the vehicle for an active agent is a implantable depot versus a tablet is irrelevant since the properties of the polymers *itself* do not change. Moreover, one would have expected Bateman's teachings to apply to Shukla since Shukla does in fact suggest that polymer blends with varying crystallinity change the release rate of the active.

For the reasons set forth above, the rejection is maintained.

Claims 1, 3, 5-7, 17-18, 34, 38, 49, 51-53, 55-56, and 58-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shukla (6,432,438) in view of US patent 5,525,646 to Lundgren et al.

Shukla teaches a biodegradable vehicle containing a drug, at least two plasticizers (solvent) selected from NMP, PEG, triacetin, etc, and at least one biodegradable polymer, which is injected into an organism. See abstract. The polymers may be selected from polyesters, polyorthoesters, polyanhydrides, polyaminoacids, pseudopolyamino acids, polyamides, polyalkylcyanoacrylates, and polyphosphazenes. A mixture of polymers may be used to tailor either the release characteristics of BAS in the biodegradable delivery system, or the degradation

characteristics of the biodegradable delivery system or both. See column 5, lines 55-67. The reference teaches the blending of two different biodegradable polymers with varying crystallinity and amorphous states to tailor release characteristics of the delivery system. See column 4, lines 25-35.column 9, lines 30-35, and examples. The method of mixing the polymer, solvent, and drug are taught in examples. Note that NMP has a miscibility of a miscibility in water of 7% or less as defined by instant specification.

Although, Shukla teaches the blending of polymers according to their properties to manipulate release rate, Shukla et al do not exemplify the use of a polymer blend consisting of an amorphous polymer and crystalline polymer. Shukla exemplifies an amorphous polymer.

Lundgren discloses a bioresorbable material and an article of manufacture made of such material for medical use to be implanted into a living organism. See column 1, lines 5-10. Lundgren et al disclose the need for implant articles to have both dimension stability (mechanical strength) to retain the shape of the implant during the healing process and malleability so that the material can take the shape of the location it is contained within. See column 1, lines 15-50. Therefore, Lundgren et al disclose a bioresorbable material that comprises at least one amorphous polymer or copolymer selected from the group consisting of poly-d,l-lactide, and copolymers of poly-d,l-lactide and polycaprolactone, poly-l-lactide, or polytrimethylene and at least one crystalline polymer selected from the group consisting of poly-l-lactide, polycaprolactone and polydioxanone; and a plasticizer (solvent). The composition is a vehicle for the delivery of active agents. See column 5, lines 40-50. Lundgren also discloses that a small amount of crystalline polymers to amorphous polymers drastically reduces swelling of the

material. Lundgren discloses that swelling has a negative influence since it forces increased pressure on the tissue and impairs mechanical strength of the implant. See column 7, lines 20-55.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Shukla et al and Lundgren and add a biodegradable crystalline polymer. One would have been motivated to do so since Lundgren teaches the criticality of having malleability and mechanical strength in an implant. Further, Lundgren teaches adding crystalline polymers to amorphous polymers reduce swelling of the implant, thus increasing mechanical strength of the implant. Therefore, one would have been motivated to add a crystalline polymer to Shukla's implant composition to provide mechanical strength to the implant once it is inserted in the body and reduce swelling of the material in the body.

Moreover, one would have been motivated to look to Lundgren's specific teaching that the instant polymer blend provides for an appropriate malleability and mechanical strength and apply it to Shukla's broad teaching of varying the properties, such as crystallinity and amorphous states, of the biodegradable polymers.

Response to Arguments

Applicant argues that Lundgren teaches away from the injectable composition and since Shukla teaches an injectable composition, the references cannot be combined.

Applicant's arguments filed 3/21/05 have been fully considered but they are not persuasive. Applicant's arguments pertaining to Lundgren teaching away from an injectable composition is not substantiated. The applicant merely argues this point without specifying the column in which Lundgren purportedly teaches away from injectable compositions. It appears applicant is assuming that a composition that is malleable and dimensionally stable is equivalent

to a teaching that it cannot be injectable. Further, it appears applicant assumes that since the polymer material is solidified prior to implanting the composition, this teaches away from an injectable composition. However, the examiner points out that Shukla's implant and the instant invention also form a solid depot after implantation. Additionally, the stability of the implant after solidification does not mean it cannot be injectable. As discussed above Lundgren is capable of being injected since the polymer material exists in a solution from until it is solidified. The fact that the implant material is solidified *prior* to implantation versus solidified *after* implantation, i.e. the method of administering the implant, is irrelevant. Moreover, the examiner points to pages 16-17 of the instant specification wherein applicant clearly states that the implant system of the invention can be administered via various methods including forming the "depot outside the body and then implant[ing] it surgically."

Secondly, the method of administering the implant does not change the examiner's motivation to combine the references. Shukla generally teaches mixing a blend of polymers to tailor either the release characteristics of biologically active substance (BAS) in the biodegradable delivery system, or the degradation characteristics of the biodegradable delivery system or both. See column 5, lines 55-67. Shukla teaches the blending of two or more different biodegradable polymers with varying crystallinity to tailor release characteristics of the delivery system and rheology of the vehicle. See column 4, lines 25-35. Moreover, Shukla teaches using blends of polymers with different crystallinity can result in a biodegradable vehicle with varying degradation rates whereas a amorphous polymer may degrade at a much faster rate that the rest of the polymers in the blend. See column 7, lines 40-45, and example 29. Although it is the examiner's position that Shukla does *suggest* the use of a crystalline polymer with a amorphous

to tailor the release rate, the examiner relies on a secondary reference, Lundgren, to provide more of a motivation for a skilled artisan to specifically utilize a mixture of an amorphous polymer and a crystalline polymer. Lundgren teaches the use of an amorphous polymer to provide malleability to the implant so that it can be adapted to the desired shape and further teaches adding a small amount of crystalline polymers to the amorphous polymers to drastically reduce swelling of the material. Lundgren discloses that swelling has a negative influence since it forces increased pressure on the tissue and impairs mechanical strength of the implant. See column 7, lines 20-55. Therefore, as stated in the rejection the motivation to add a crystalline polymer is to increase the mechanical strength of the implant.

For the reasons above, the rejection is maintained.

Claims 1, 3-18, 17-19, 34, 38, and 49-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 6,130,200 to Brodbeck et al in view of US patent 5,525,646 to Lundgren et al or vice-versa wherein the claims of 3-4, 8, 19, 49-50, 54, 57, 59, 61-65, 68-72 are rejected over Lundgren in view of Brodbeck.

Brodbeck et al disclose an injectable gel composition containing a biocompatible polymer(s), ethyl or benzyl benzoate, instant biocompatible component solvent , a bioactive agent, and an emulsifier for the active agent. See column 7, lines 25-35 and column 13, lines 50-65. (Note Examples, Tables 1-2) Brodbeck teaches biodegradable polymers include polylactides, polyglycolides, polyanhydrides, polydioxanones, polycaprolactone, PVP, etc. and mixtures thereof. See column 10, lines 65-68. Brodbeck teaches a solvent having a solubility in water of less than 7% allows for suitable burst control and sustained release of the beneficial agent. The invention is directed to a method of systemically or locally administering a beneficial agent to a

subject by implanting the gel into the subject. Lastly, Brodbeck teaches that rapid water intake into a polymer implant can result in an implant with pore structures causing a burst effect. See column 4, lines 24-40.

Although Brodbeck teaches mixtures of biodegradable polymers, does not specifically teach the instant polymer blend of an amorphous polymer with a crystalline polymer.

Lundgren discloses a bioresorbable material and an article of manufacture made of such material for medical use to be implanted into a living organism. See column 1, lines 5-10. Lundgren et al disclose the need for implant articles to have both dimension stability (mechanical strength) to retain the shape of the implant during the healing process and malleability so that the material can take the shape of the location it is contained within. See column 1, lines 15-50. Therefore, Lundgren et al disclose a bioresorbable material that comprises at least one amorphous polymer or copolymer selected from the group consisting of poly-d,l-lactide, and copolymers of poly-d,l-lactide and polycaprolactone, poly-l-lactide, or polytrimethylene and at least one crystalline polymer selected from the group consisting of poly-l-lactide, polycaprolactone and polydioxanone; and a plasticizer (solvent). The composition is a vehicle for the delivery of active agents. See column 5, lines 40-50. Lundgren teaches the use of only the amorphous polymer causes water swelling which effects the stability and causes the implant to have pores, perforations, depressions, etc. See the entire discussion spanning 5-7. Lundgren discloses that a small amount of crystalline polymers to amorphous polymers drastically reduces swelling of the material. Lundgren discloses that swelling has a negative influence since it forces increased pressure on the tissue and impairs mechanical strength of the implant. See column 7, lines 20-55.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Brodbeck et al and Lundgren and utilize a combination of an amorphous polymer and a crystalline polymer. One would have been motivated to do so since Lundgren teaches the criticality of having malleability and mechanical strength a biodegradable implant. Lundgren teaches that the use of an amorphous polymer provides malleability so that the implant can be formed to the desired shape and fit the implanting region but the sole use of an amorphous polymer causes instability of an implant by creating pores, perforations, etc. Thus, Lundgren teaches adding crystalline polymers to amorphous polymers to reduce swelling of the implant, thus increasing mechanical strength of the implant. Therefore, one would have been motivated to add a crystalline polymer to Brodbeck's implant composition to provide mechanical strength to the implant once it is inserted in the body and reduce swelling of the material in the body. Further, one would have reasonably expected success by combining the references since Brodbeck recognizes that polymer implants suffer from instability caused by swelling and provides a solution and although Brodbeck provides one solution to the problem, a skilled artisan would have been motivated to further prevent water uptake by adding a crystalline polymer.

Conversely, it would have been obvious to utilize the instant biocompatible solvent and emulsifying agent of Brodbeck's in Lundgren's formulation. One would have been motivated to utilize an emulsifying agent since Brodbeck teaches on column 6, lines 55-60 the use of an emulsifying agent to emulsify the active agent into the polymer. Further, one would have been motivated to utilize the instant solvent and biocompatible solvent to further reduce the water intake of the implant and prevent an unwanted burst effect as taught by Brodbeck.

Response to Arguments

Applicant argues that Lundgren teaches away from the injectable composition and since Brodbeck teaches an injectable composition, the references cannot be combined.

Applicant's arguments filed 3/21/05 have been fully considered but they are not persuasive. Applicant's arguments pertaining to Lundgren teaching away from an injectable composition is not substantiated. The applicant merely argues this point without specifying the column in which Lundgren purportedly teaches away from injectable compositions. It appears applicant assumes that since the polymer material is solidified prior to implanting the composition, this teaches away from an injectable composition. However, the examiner points out that Shukla's implant and the instant invention also form a solid depot after implantation. Also, discussed above Lundgren is capable of being injected since the polymer material exists in a solution from until it is solidified. The fact that the implant material is solidified *prior* to implantation versus solidified *after* implantation, i.e. the method of administering the implant, is irrelevant since both references are directed to bioresorbable polymer implants. Moreover, the examiner points to pages 16-17 of the instant specification wherein applicant clearly states that the implant system of the invention can me administered various methods including forming the "depot outside the body and then implant[ing] it surgically."

Secondly, the method of administering the implant does not change the examiner's motivation to combine the references. Brodbeck generally teaches the implant may have a blend of polymers. Moreover, Brodbeck teaches that rapid water intake into a polymer implant can result in an implant with pore structures causing a burst effect. See column 4, lines 24-40. The examiner relies on Lundgren, to provide more of a motivation for a skilled artisan to specifically

utilize a mixture of an amorphous polymer and a crystalline polymer. Lundgren teaches the use of an amorphous polymer to provide malleability to the implant so that it can be adapted to the desired shape. However, Lundgren teaches the use of only the amorphous polymer causes water swelling which effects the stability and causes the implant to have pores, perforations, depressions, etc. See the entire discussion spanning 5-7 and especially column 7, lines 45-55. Lundgren teaches adding a small amount of crystalline polymers to the amorphous polymers to drastically reduce swelling of the material. Lundgren discloses that swelling has a negative influence since it forces increased pressure on the tissue and impairs mechanical strength of the implant. See column 7, lines 20-55. Therefore, as stated in the rejection the motivation to add a crystalline polymer is to increase the mechanical strength of the implant. Further, both Brodbeck and Lundgren both recognize the detrimental effect of rapid water intake and Lundgren provides one solution for to reduce the swelling.

For the reasons above, the rejection is maintained.

Conclusion

All the claims are rejected at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616

SSG

Gary d. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600